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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,962	08/22/2003	David Farrar	PT-2683-US-NP	8400
68622	7590	07/13/2009	EXAMINER	
NORMAN F. HAINER, JR. SMITH & NEPHEW, INC. 150 MINUTEMAN ROAD ANDOVER, MA 01801			STROUD, JONATHAN R	
			ART UNIT	PAPER NUMBER
			3774	
			MAIL DATE	DELIVERY MODE
			07/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/645,962

Applicant(s)

FARRAR ET AL.

Examiner

JONATHAN R. STROUD

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/16/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8-11 and 51-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,8-11 and 51-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 04/16/2009 have been fully considered but they are not persuasive.
2. Applicant's arguments are threefold. First, applicant argues that the examiner is incorrect in indicating that the two materials disclosed in the prior art have different relative rates of *in vivo* degradation. Second, applicant argues that Brown does not disclose a device that, when initially implanted, does not have sufficient porosity to support tissue ingrowth. Third, applicant argues that the differences in numerical rates of degradation are in fact patentable, since, as applicant contends, the device in the prior art Brown does not disclose having different relative rates of *in vivo* degradation.
3. Re the first argument, examiner maintains that Brown implicitly gives various ceramics and polymers which all have well-known rates of degradation, and of which almost all combinations, if not all, have different relative rates of *in vivo* degradation. For instance, pars. [0034, 0036] indicate a list of ceramics and polymers one skilled in the art could select from; for instance, hydroxyapatite and collagen. Both have well-known properties in the body; hydroxyapatite for its ability to withstand degradation and mimic cancellous bone; and collagen for its flexibility and biocompatibility, and also its fast degradation time. This is merely an instructive example of the many disclosed examples in pars. [0034, 0036]. Still further, pars. [0046, 0047] disclose polymer absorption times and discuss the reabsorption of the polymer phase in a timely fashion; i.e., faster than the absorption of the ceramic element.

4. Re the second argument, Brown teaches a macro-porous ceramic whose pores are mostly filled with what can be a microporous polymer foam. However, Brown further discloses a foam that is impervious, para. [0064], on the surface porosity. Further, Brown discloses the possibility of varying porosity, which may have a closed-cell configuration, para. [0067]. Still further, Brown discloses the ceramic macroporous phase can be filled with biocompatible ceramic materials, xenographic bone, and the like, para. [0056]. If that is the case, when initially implanted, the device of Brown would lack sufficient porosity to support tissue growth. Further, the term "support" tissue growth leaves open the possibility that tissue growth may be occurring without being fully supported or "sustained", as is often the case with devices that must be re-implanted. Still further, the size of the pores and shape of the pores, or the porosity necessary to support tissue ingrowth, is in part dependent on where and what body the device is implanted in, and thus leaves the claim interpretation open to a variant reading of "the device ...does not have sufficient porosity to support tissue growth". If implanted in a certain body, or in a block of stone, for instance, the device will never have sufficient porosity to support tissue ingrowth.
5. Re the third argument, see the response to the first argument; Brown does in fact disclose having different relative rates of in vivo degradation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 8, 11, 51-55 rejected under 35 U.S.C. 102(a/e) as being anticipated by Brown 2003/0003127.
2. Brown teaches a unitary perform device, 10, made up of a composite scaffold of a porous ceramic phase base, abstract, and a porous polymer phase, abstract.
3. Brown teaches that the polymer phase infiltrates the macropores of the ceramic phase, para. 0026, forming a solid interlocking perform structure.
4. Brown teaches that a ceramic that is free of micropores and has macropores that are filled by polymer phase, 0026, and a polymer phase that has only micropores, so that the final ceramic/polymer base is "substantially" non-porous.
5. Brown teaches a therapeutic additive, para. 0058.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown 2003/0003127.

Brown teaches a polymer/ceramic perform with differing rates of degradation.

Brown is silent as to the numerical rates of degradation, but discloses various materials.

The optimization within prior art conditions is obvious to one of ordinary skill in the art. See MPEP 2144.05. Further, the selection of a material or equivalent recognized in the prior art supports a prima facie case of obviousness. See MPEP 2144.06.

8. Claims 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown 2003/0003127, further in view of Evans 2003/0236573.

9. Brown teaches the device as claimed and as discussed above, but does not teach a device that is completely non-porous when initially implanted or a device that fills the interconnected pores throughout the entire ceramic structure. Brown teaches a zone where the interconnected pores throughout the entire ceramic structure are filled, and a zone where they are not.

Evans teaches that it may be desirable to have non-porous portions of the implant, and further, specifically, an implant which is initially a porous resorbable macrostructure, where the pores of the device are filled, with a microstructure that degrades more rapidly, so that the porosity is then revealed, for the purpose of

controlling the porosity of the device along a timeline that is related to the various rates of in vivo degradation.

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the two-material ceramic-polymer scaffold structure of Brown in view of Evans, to teach that it may be desirable to have non-porous portions of the device as well, and further, that it may be desirable to have an implant which is comprised of two materials, only one of which is macroporous, which is then filled by a secondary material, so that when the secondary material is degraded, the porosity is then revealed.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN R. STROUD whose telephone number is (571)270-3070. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 6 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan R Stroud/
Examiner, Art Unit 3774
/William H. Matthews/ (hoteling)
Primary Examiner, Art Unit 3774